

### **Remarks**

Claims 1, 4, 7-9, 11, 12, 23, 28-31, and 33-36 are pending and stand rejected. Claims 1, 4, 8, 9, 23, 30, and 33 have been amended. Claims 34-36 have been canceled. No new matter has been added by these amendments.

Applicants acknowledge and appreciate the Examiner's withdrawal of finality and the Examiner's withdrawal of the rejections under 35 U.S.C. 103(a) and the judicially-created doctrine of obviousness-type double patenting.

It appears as if no Power of Attorney had been previously submitted in this application. Therefore, appropriate Power of Attorney and Statement Under 3.73(b) forms are submitted herewith. Terminal disclaimers over U.S. Patent Application No. 11/473,386 and U.S. Patent No. 7,090,867 are also resubmitted herewith.

### **Claim Rejections Under 35 U.S.C. § 112, first paragraph**

Claims 1, 4, 7-9, 11-12, 23, 28-31, and 33-36 stand rejected as allegedly failing to comply with 35 U.S.C. 112, first paragraph. The Applicant respectfully traverses.

Claim 1 has been amended to specify the relative amounts of crosslinked acrylic acid polymers, hydroxyethyl cellulose/hydroxypropylmethyl cellulose, talc, and magnesium stearate. Similar limitations have been added where appropriate in claims 9, 23, 30, and 33. Support for these amendments may be found on pages 2-4 of the specification as filed.

The Examiner states that the subject matter relating to "about 1% to 58% by weight of a mixture of hydroxyethyl cellulose and hydroxypropyl methyl cellulose" was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors has possession of the claimed invention at the time the application was filed. Applicant respectfully traverses. The limitation of "about 1% to 58% by weight" is supported at least by the examples. Specifically, example 1 describes a formulation with 58% hydroxyethyl cellulose/hydroxypropylmethyl cellulose (HEC/HMPC), Example 2 discloses 50% HEC/HMPC and example 3 discloses 55% HEC/HMPC. In support of the lower limitation of this range, the

specification recites that a composition that may comprise “about 1 to 75% by weight uncrosslinked, linear water soluble polymers” (page 3, line 31), and hydroxyethyl cellulose and hydroxypropylmethyl cellulose are identified as examples of these polymers (page 4, lines 25-27). Thus, the specification as filed provides ample support for the recited range.

The Examiner also alleges that the support for the following language lacks adequate description in the specification: “wherein said acrylic acid crosslinked polymers, hydroxyethyl cellulose and hydroxypropylmethyl cellulose, talc, magnesium stearate...are provided in a homogeneous mixture.” The Applicant respectfully traverses. The specification clearly recites that the active agent and uncrosslinked polymer mixture is to be “intimately blended” with a crosslinked polymer (page 5, lines 14-15), which mixture is to be “intimately blended” with a glidant such as talc (page 5, line 17), which mixture is finally “intimately blended” with a lubricant such as magnesium stearate (page 5, lines 18-19). Importantly, the starting mixture of active agent and uncrosslinked polymers is said to be “intimately blended...until a homogeneous mixture is formed” (page 5, lines 3-7). Importantly, due to the consistent use of the same language (i.e., “intimately blended”), one of ordinary skill in the art would have understood that the final mixture of the recited components was formed into a homogeneous mixture.

Claims 4, 9, and 30 have been amended to recite specific language from the specification with respect to properties of the crosslinked acrylic acid polymers. Support for these amendments may be found on page 4 of the specification as filed, at lines 29-31.

Claims 8, 9, and 30 have been amended to recite specific language from the specification regarding the quantity of granulating and tableting aids present in compositions of the invention. Support for these amendments may be found at least on page 3, at line 6, of the specification as filed.

For the reasons set forth above, Applicant respectfully requests withdrawal of the rejections under § 112.

**Conclusion**

In view of the above amendments and remarks, the Applicant believes that the pending claims are in condition for allowance. If a telephone conference would be helpful, the Examiner is invited to call the undersigned at 617-832-1000. Applicant hereby requests that any additional fees required for timely consideration of this application be charged to **Deposit Account No. 06-1448, Reference SMI-005.01.**

Respectfully submitted,

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Date: October 25, 2010

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